

ARTICLE

EPA Fast Tracks “Long-Lasting” Antiviral Products for Use Against COVID-19

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Companies interested in anti-microbial products and innovating during the COVID-19 pandemic should note a recent change in the U.S. Environmental Protection Agency’s (EPA) review process for long-lasting residual antimicrobial products that kill pathogens on treated hard surfaces. Late last week, EPA’s Office of Pesticide Programs – the office that regulates anti-microbial products – published interim guidance announcing a new and expedited review process for these products. All cleaning and disinfecting products claiming to kill viruses and/or bacteria must be registered with EPA as pesticides before they can be sold or distributed – a process through which EPA reviews testing data to ensure that products work as intended without causing unreasonable risks. As a part of the registration process, EPA pre-approves all claims made on the labels of registered products.

The newly released guidance follows EPA’s approval in late August of a long-lasting surface disinfectant against SARS-CoV-2 (Coronavirus) – SurfaceWise2 – registered under emergency authority for limited use in Texas. The SurfaceWise2 product is a surface coating that inactivates viruses and bacteria within two hours of application and continues to work against them for up to seven days. Other products with residual effect claim to provide anti-microbial protection for weeks, or even years after the product is applied to the surface. Products that effectively provide such long-lasting residual effects are potential game changers in fighting the coronavirus – particularly in efforts to disinfect frequently touched hard surfaces in public spaces such as stores, schools, offices, airplanes, trains, buses, etc.

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EPA has many years of experience with reviewing and regulating traditional cleaning and disinfecting products used to kill viruses and bacteria, and it has been expediting the approval of such products for use on SARS-CoV-2 during the pandemic under its Emerging Viral Pathogen Policy. Under that policy, a company can apply for an *emerging viral pathogen* (i.e., SARS-CoV-2) claim, even before an outbreak occurs, based on previous EPA-approved claims for harder-to-kill *viruses*. EPA has less experience with anti-microbial products claiming to provide long-lasting (residual) control. In the past, EPA has reviewed and approved anti-microbial products for long-lasting (residual) control against bacteria. But, until it approved the use of SurfaceWise2 under its Section 18 authority, it had never approved a product for residual control against a virus.

EPA’s new guidance is specifically aimed at two categories of products that can demonstrate “extended” or “long-lasting” surface protection against viruses like SARS-CoV-2:

1. Supplemental Residual Antimicrobial Products – supplemental products that can offer protection for weeks or even years (e.g., coatings, paints, solid surfaces that do not meet EPA’s disinfectant standards but can be used to supplement standard List N disinfectant).
2. Residual Disinfectants – disinfectants that also provide residual efficacy.

EPA’s guidance sets out a framework for the kinds of scientific data and study design elements it requires to provide expedited review and processing of Residual Disinfectants and Supplemental Residual Antimicrobial Products. These include, compliance with a modified version of EPA’s Residual Self-Sanitization Protocol and mandated label claims. EPA has warned would-be applicants that in order to expedite submissions, it is necessary for EPA to receive all of the information specified in the interim guidance. However, the Agency has stated that it will consider other methods or studies to support residual efficacy claims that are scientifically sound. If all required information is received, EPA estimates being able to shorten normal processing times for antimicrobial products that may be of use against SARS-CoV-2 by at least one to two months.

EPA began expediting the registration process for Residual Disinfectants and Supplemental Residual Antimicrobial Products immediately on October 14 and may revise its interim guidance after a 60-day public comment period.

Wiley continues to work with companies on COVID-19 response consumer products like disinfectants, sanitizers, respirators, and test kits. If you would like to sign up to receive our Coronavirus Updates, [click here](#).